

Due-Diligence Checklist

How does your pharmacy compare?

- ✓ We perform sterility and potency testing on Injectable preparations.
- ✓ We perform pH testing on all Injectables as well as all other necessary compounds.
- ✓ We verify the potency of finished compounds through weight, volume and yield checks. We perform HPLC validation on all sterile formulations.
- ✓ All compounds are put through a validated Quality control process.
- ✓ We only utilize pharmaceutical-grade chemicals/raw materials (USP) from FDA registered suppliers.
- ✓ Our entire compounding process is overseen by an authorized & licensed Pharmacist.
- ✓ We maintain both master formulas and lot-specific worksheets for all compounds. They include the manufacturer and lot number of each ingredient and quality-control test result.
- ✓ We can trace a prescription back to the original formula log sheet and the source of ingredients.
- ✓ We conduct independent, semi-annual certifications of our clean rooms and laminar airflow hoods.
- ✓ We utilize Class100 laminar airflow hoods inside our state-of-the-art class 1000 clean room achieving .2 micron filtration.
- ✓ We perform post-filtration filter-integrity testing.
- ✓ We conduct monthly independent lab tests of air and surface samples in our clean rooms.
- ✓ Our staff is fully trained and validated in proper gowning and aseptic techniques, clean room regulations and USP Guidelines.

Our quality control process far exceeds that of many Compounding Pharmacies in the United States. All of our (USP) raw material sources come from reliable FDA registered facilities. It is important to choose a Pharmacy that adheres to the highest levels of compliance directly ensuring your client is receiving the best quality product available.

We have implemented a state of the art HPLC, UV Spectrophotometer Gas Chromatograph with Mass Spectrophotometer and Infrared Spectrophotometer that will be used to fully certify and provide audit trails for the FDA and Board of Pharmacy inspection. Having an in-house HPLC allows us to conduct "in process testing," a clear advantage to making adjustments that ensure the appropriate final results.

We pride ourselves in compounding the finest preparations for both Human and Veterinary use. Our in house Bio-Chemist and Micro-Biologist ensure you the highest quality control possible.

- ✓ Our general compounding lab is engineered with HEPA filtration systems to reduce particulates.
- ✓ We are fully Licensed, Bonded and Insured for your safety.
- ✓ We have completed the 797 Gap Analysis.
- ✓ We perform daily monitoring and documentation of our clean-room temperature and humidity.
- ✓ We perform USP 71 and USP 85 procedures.
- ✓ In the event of sterility failure, complaint or adverse event, we have a procedure in place for determining and conducting a recall, if necessary.
- ✓ We are a member of the PCCA, IACP.